

## Complete Summary

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### GUIDELINE TITLE

Standards of medical care in diabetes. VII. Diabetes care in specific populations.

### BIBLIOGRAPHIC SOURCE(S)

Standards of medical care in diabetes. VII. Diabetes care in specific populations.  
Diabetes Care 2005 Jan; 28(suppl 1):s21-4.

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Preconception care of women with diabetes. Diabetes Care 2004 Jan; 27(Suppl 1):S76-8.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

- Type 1 and type 2 diabetes mellitus
- Complications of diabetes mellitus including:
  - Nephropathy
  - Hypertension
  - Dyslipidemia
  - Retinopathy
- Pregnancy

### GUIDELINE CATEGORY

Evaluation  
Management  
Prevention  
Risk Assessment  
Screening  
Treatment

#### CLINICAL SPECIALTY

Cardiology  
Endocrinology  
Family Practice  
Geriatrics  
Internal Medicine  
Nephrology  
Nutrition  
Obstetrics and Gynecology  
Ophthalmology  
Pediatrics

#### INTENDED USERS

Advanced Practice Nurses  
Allied Health Personnel  
Dietitians  
Nurses  
Physician Assistants  
Physicians  
Social Workers

#### GUIDELINE OBJECTIVE(S)

- To provide recommendations for diabetes care in specific populations with respect to:
  - Screening and treating complications in children and adolescents with type 1 diabetes mellitus
  - Preconception care in women
  - Management of diabetes in older individuals
- To provide clinicians, patients, researchers, payers, and other interested persons with the components of diabetes care, treatment goals, and tools to evaluate the quality of care

#### TARGET POPULATION

- Children and adolescents with type 1 diabetes mellitus
- Diabetic women of child-bearing age
- Older individuals (>65 years of age) (no specific recommendations provided)

#### INTERVENTIONS AND PRACTICES CONSIDERED

## Screening for Complications in Children and Adolescents with Type 1 Diabetes Mellitus

1. Screening for microalbuminuria (urine microalbumin-to-creatinine ratio)
2. Screening for dyslipidemia (fasting lipid profile)
3. Screening for retinopathy (ophthalmologic examination)

## Management/Treatment of Diabetes Complications in Children and Adolescents

1. Angiotensin-converting enzyme (ACE) inhibitor
2. Lifestyle interventions
  - Dietary intervention
  - Exercise
3. Medical nutrition therapy (MNT) aimed at decreased intake of saturated fats
4. Anti-hypertensive agents
5. Lipid-lowering agents

## Preconception Care

1. Attainment of target A1C levels before conception
2. Patient education/family planning
3. Preconception evaluation and treatment of diabetic retinopathy, nephropathy, neuropathy, and cardiovascular disease (CVD)
4. Discontinuation of drugs contraindicated in pregnancy

## Management of Diabetes in Older Individuals

Glycemic control, blood pressure, and lipid control (considered, but not recommended)

## MAJOR OUTCOMES CONSIDERED

- Risk and rate of congenital malformations
- Risk and rate of early pregnancy loss
- Blood glucose levels
- Blood pressure levels
- Lipid levels
- Patient adherence
- Morbidity and mortality

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

## NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

American Diabetes Association's evidence grading system for clinical practice recommendations:

### A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford\*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

\*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

### B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

### C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses  
Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see "Rating Scheme for the Strength of the Evidence"). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved in October 2004 by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

#### Children and Adolescents

##### Type 1 Diabetes

##### Glycemic Control

Table: Plasma blood Glucose and A1C Goals for Type 1 Diabetes By Age Group

	Plasma blood glucose goal range (mg/dL)			
Values by age (years)	Before meals	Bedtime/overnight	A1C (%)	Rationale
Toddlers and preschoolers (<6)	100-180	110-200	≤8.5 (but ≥7.5%)	<ul style="list-style-type: none"><li>• High risk and vulnerability to hypoglycemia</li></ul>
School age (6-12)	90-180	100-180	<8%	<ul style="list-style-type: none"><li>• Risks of hypoglycemia and relatively low risk of complications prior to puberty</li></ul>
Adolescents and young adults (13-19)	90-130	90-150	<7.5%*	<ul style="list-style-type: none"><li>• Risk of hypoglycemia</li><li>• Developmental and psychological issues</li></ul>

#### Key concepts in setting glycemic goals:

- Goals should be individualized and lower goals may be reasonable based on benefit:risk assessment.
- Blood glucose goals should be higher than those listed above in children with frequent hypoglycemia or hypoglycemia unawareness.
- Postprandial blood glucose values should be measured when there is a disparity between pre-prandial blood glucose and A1C levels.

\*A lower goal (<7.0%) is reasonable if it can be achieved without excessive hypoglycemia.

## Screening and Management of Chronic Complications in Children and Adolescents with Type 1 Diabetes

### Nephropathy

- Annual screening for microalbuminuria should be initiated once the child is 10 years of age and has had diabetes for 5 years. Screening may be done with a random spot urine sample analyzed for microalbumin-to-creatinine ratio. (E)
- Confirmed, persistently elevated microalbumin levels should be treated with an angiotensin-converting enzyme (ACE) inhibitor, titrated to normalization of microalbumin excretion (if possible). (E)

### Hypertension

- Treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) should include dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached within 3-6 months of lifestyle intervention, pharmacologic treatment should be initiated. (E)
- Pharmacologic treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height, or consistently >130/80, if 95% exceeds that value) should be initiated as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension. (E)

### Dyslipidemia

#### Screening

- Prepubertal children: a fasting lipid profile should be performed on all children >2 years of age at the time of diagnosis (after glucose control has been established) if there is a family history of hypercholesterolemia (total cholesterol >240 mg/dL) or a history of a cardiovascular event before age 55 years, or if family history is unknown. If family history is not of concern, then the first lipid screening should be performed at puberty (>12 years). If values fall within the accepted risk levels (low density lipoprotein [LDL] <100 mg/dL; 2.6 mmol/L), a lipid profile should be repeated every 5 years. (E)
- Pubertal children (>12 years old): a fasting lipid profile should be performed at the time of diagnosis (after glucose control has been established). If values fall within the accepted risk levels (LDL <100 mg/dL; 2.6 mmol/L), the measurement should be repeated every 5 years. (E)
- If lipids are abnormal, annual monitoring is recommended in both age groups. (E)

#### Treatment

- Treatment should be based on fasting lipid levels (mainly LDL) obtained after glucose control is established. (E)
- Initial therapy should consist of optimization of glucose control and medical nutrition therapy (MNT) aimed at a decrease in the amount of saturated fat in the diet. (E)
- The addition of pharmacologic lipid-lowering agents is recommended for LDL >160 mg/dL (4.1 mmol/L) and is also recommended in patients who have LDL cholesterol values 130-159 mg/dL (3.4-4.1 mmol/L) based on the patient's cardiovascular disease (CVD) risk profile, after failure of medical nutrition therapy (MNT) and lifestyle changes. (E)
- The goal of therapy is an LDL value <100 mg/dL (2.6 mmol/L). (E)

### Retinopathy

- The first ophthalmologic examination should be obtained once the child is 10 years of age or older and has had diabetes for 3-5 years. (E)
- After the initial examination, annual routine follow-up is generally recommended. Less frequent examinations may be acceptable on the advice of an eye care professional. (E)

### Preconception Care

- A1C levels should be normal or as close to normal as possible (<1% above the upper limits of normal) in an individual patient before conception is attempted. (B)
- All women with diabetes and childbearing potential should be educated about the need for good glucose control before pregnancy. They should participate in family planning. (E)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (E)
- Among the drugs commonly used in the treatment of patients with diabetes, statins are pregnancy category X and should be discontinued before conception if possible. Angiotensin-converting enzyme inhibitors and angiotensin receptor blockers (ARBs) are category C in the first trimester (maternal benefit may outweigh fetal risk in certain situations), but category D in later pregnancy, and should generally be discontinued prior to pregnancy. Among the oral antidiabetic agents, metformin and acarbose are classified as category B and all others as category C; potential risks and benefits of oral antidiabetic agents in the preconception period must be carefully weighed, recognizing that sufficient data are not available to establish the safety of these agents in pregnancy. They should generally be discontinued in pregnancy. (E)

### Older Individuals

Diabetes is an important health condition for the aging population; at least 20% of patients over the age of 65 years have diabetes. The number of older individuals with diabetes can be expected to grow rapidly over the coming decades. A recent publication, "Guidelines for Improving the Care of the Older Person with Diabetes," contains evidence-based guidelines produced in conjunction with the American Geriatric Society. This document contains an



excellent discussion of this area, and specific guidelines and language from it have been incorporated in the original guideline document. Unfortunately, there are no long-term studies in individuals >65 years of age demonstrating the benefits of tight glycemic control, blood pressure, and lipid control. Older individuals with diabetes have higher rates of premature death, functional disability, and coexisting illnesses such as hypertension, coronary heart disease (CHD), and stroke than those without diabetes. Older adults with diabetes are also at greater risk than other older adults for several common geriatric syndromes, such as polypharmacy, depression, cognitive impairment, urinary incontinence, injurious falls, and persistent pain.

The care of older adults with diabetes is complicated by their clinical and functional heterogeneity. Some older individuals developed diabetes in middle age and face years of comorbidity; others who are newly diagnosed may have had years of undiagnosed comorbidity or few complications from the disease. Some older adults with diabetes are frail and have other underlying chronic conditions, substantial diabetes-related comorbidity, or limited physical or cognitive functioning, but other older adults with diabetes have little comorbidity and are active. Life expectancies are also highly variable for this population. Clinicians caring for older adults with diabetes must take this heterogeneity into consideration when setting and prioritizing treatment goals.

All this having been said, patients who can be expected to live long enough to reap the benefits of long-term intensive diabetes management (approximately 10 years) and who are active, cognitively intact, and willing to undertake the responsibility of self-management should be encouraged to do so and be treated using the stated goals for younger adults with diabetes.

#### Definitions:

American Diabetes Association's evidence grading system for clinical practice recommendations:

#### A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford\*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

\*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each specific recommendation (see the "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Preconception care of diabetes appears to reduce the risk of congenital malformations.
- Appropriate detection and management of diabetes complications in children and adolescents

## POTENTIAL HARMS

Among the drugs commonly used in the treatment of patients with diabetes, statins are pregnancy category X and should be discontinued before conception if possible. Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) are category C in the first trimester (maternal benefit may outweigh fetal risk in certain situations) but category D in later pregnancy and should generally be discontinued before pregnancy.

## CONTRAINDICATIONS

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Statins are pregnancy category X and should be discontinued before conception, if possible.

## QUALIFYING STATEMENTS

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- Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by American Diabetes Association, may miss some nuances that are important in diabetes care.
- While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more extensive evaluation and management of the patient by other specialists as needed.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in important outcomes such as A1C measurements and blood pressure and lipid determinations as well as process measures such as provision of eye exams. Successful interventions have been focused at the level of health care professionals, delivery systems, and patients. Features of successful programs reported in the literature include:

- Improving health care professional education regarding the standards of care through formal and informal education programs.

- Delivery of diabetes self-management education (DSME), which has been shown to increase adherence to standard of care.
- Adoption of practice guidelines, with participation of health care professionals in the process. Guidelines should be readily accessible at the point of service, such as on patient charts, in examining rooms, in "wallet or pocket cards," on PDAs, or on office computer systems. Guidelines should begin with a summary of their major recommendations instructing health care professionals what to do and how to do it.
- Use of checklists that mirror guidelines have been successful at improving adherence to standards of care.
- System changes, such as provision of automated reminders to health care professionals and patients, reporting of process and outcome data to providers, and especially identification of patients at risk because of failure to achieve target values or a lack of reported values.
- Quality improvement programs combining Continuous Quality Improvement (CQI) or other cycles of analysis and intervention with provider performance data.
- Practice changes, such as clustering of dedicated diabetes visits into specific times within a primary care practice schedule and/or visits with multiple health care professionals on a single day and group visits.
- Tracking systems either with an electronic medical record or patient registry have been helpful at increasing adherence to standards of care by prospectively identifying those requiring assessments and/or treatment modifications. They likely could have greater efficacy if they suggested specific therapeutic interventions to be considered for a particular patient at a particular point in time.
- A variety of non-automated systems such as mailing reminders to patients, chart stickers, and flow sheets have been useful to prompt both providers and patients.
- Availability of case or (preferably) care management services, usually by a nurse. Nurses, pharmacists, and other non-physician health care professionals using detailed algorithms working under the supervision of physicians and/or nurse education calls have also been helpful. Similarly dietitians using medical nutrition therapy (MNT) guidelines have been demonstrated to improve glycemic control.
- Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.

Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. Therefore, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of health care professionals.

## IMPLEMENTATION TOOLS

### Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness  
Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Standards of medical care in diabetes. VII. Diabetes care in specific populations.  
Diabetes Care 2005 Jan;28(suppl 1):s21-4.

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1995 (revised 2005 Jan)

### GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

### SOURCE(S) OF FUNDING

The American Diabetes Association (ADA) received an unrestricted educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2004 Diabetes Care Supplement.

### GUIDELINE COMMITTEE

Professional Practice Committee

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Preconception care of women with diabetes. Diabetes Care 2004 Jan; 27(Suppl 1): S76-8.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Diabetes Association \(ADA\) Web site](#).

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. Diabetes Care 28:S1-S2, 2005
- Strategies for improving diabetes care. Diabetes Care 28:S30-S31, 2005.

Electronic copies: Available from the [American Diabetes Association \(ADA\) Web site](#).

The following is also available:

- 2005 clinical practice recommendations standards of care. Personal digital assistant (PDA) download. Available from the [American Diabetes Association \(ADA\) Web site](#).

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. This summary was updated by ECRI on January 29, 2002, April 21, 2003, March 23, 2004, and July 1, 2005. The updated information was verified by the guideline developer on August 1, 2005.

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